

## **IN THE CLAIMS**

No claims have been cancelled or amended by this paper. The pending claims therefore remain as follows:

1. A method of implanting material in an intervertebral disc nucleus space; the method comprising:

(a) providing a disc nucleus implant instrument having:

(i) a passageway effective for passing a material for replacing or augmenting an intervertebral disc nucleus, said passageway having a proximal end and a distal end; and

(ii) a dilator at the distal end of said passageway, said dilator being effective for dilating an opening in a disc annulus;

(b) providing a material suitable for replacing or augmenting an intervertebral disc nucleus in the passageway of said disc nucleus implant instrument;

(c) providing a hole in the annulus of a disc receiving the material for replacing or augmenting an intervertebral disc nucleus, said hole having an undilated size that is smaller than the cross-sectional size of the material for replacing or augmenting an intervertebral disc nucleus, and said hole having a dilated size that is larger than the cross-sectional size of the material for replacing or augmenting an intervertebral disc nucleus;

(d) introducing the dilator of said disc nucleus implant instrument into the hole in the disc annulus while said hole is not fully dilated;

(e) causing said dilator to dilate, and thus to dilate the hole in the disc annulus;

(f) passing said material for replacing or augmenting an intervertebral disc nucleus through said dilator and into said disc nucleus space while the hole in said disc annulus is dilated; and

(g) withdrawing said disc nucleus implant instrument and allowing said hole in said disc annulus to return to a size smaller than its dilated size.

2. The method of claim 1 wherein said dilator comprises at least two arms for dilating a hole in a disc annulus.

3. The method of claim 2 wherein at least one of said at least two arms is fixed with respect to said passageway for passing a prosthetic disc nucleus.

4. The method of claim 2 wherein at least two of said at least two arms are movable with respect to said passageway for passing a prosthetic disc nucleus.

5. The method of claim 1 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate; and wherein the method further includes the step of activating the activator to dilate the dilator.

6. The method of claim 5 wherein said activator includes a lever for activating said dilator.

7. The method of claim 5 wherein said activator includes an inclined plane for activating said dilator.

8. The method of claim 5 wherein said activator includes a screw for activating said dilator.

9. The method of claim 2 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate; and wherein the method

further includes the step of activating the activator to move at least one of said at least two arms to dilate a hole in a disc annulus.

10. The method of claim 9 wherein at least one of said at least two arms is fixed with respect to said passageway for passing a prosthetic disc nucleus.

11. The method of claim 9 wherein at least two of said at least two arms are movable with respect to said passageway for passing a prosthetic disc nucleus.

12. The method of claim 9 wherein said activator includes a lever for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

13. The method of claim 9 wherein said activator includes an inclined plane for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

14. The method of claim 9 wherein said activator includes a screw for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

15. The method of claim 1 wherein said disc nucleus implant instrument further includes a locking mechanism for holding said dilator in a dilating position.

16. A method of implanting a prosthetic spinal disc nucleus in an intervertebral disc nucleus space; the method comprising:

(a) providing a disc nucleus implant instrument having:

(i) a passageway for passing a prosthetic disc nucleus, said passageway having a proximal end and a distal end; and

(ii) a dilator at the distal end of said passageway, said dilator being effective for dilating an opening in a disc annulus;

(b) providing a prosthetic disc nucleus having a first configuration and a second configuration, wherein said first configuration presents a first cross-sectional size and said second configuration presents a second cross-sectional size, wherein said first cross-sectional size is larger than said second cross-sectional size;

(c) providing a hole in the annulus of a disc receiving the prosthetic disc nucleus, said hole having an undilated size that is smaller than the first cross-sectional size of said prosthetic disc nucleus, and said hole having a dilated size that is larger than the second cross-sectional size of said prosthetic disc nucleus;

(d) providing said prosthetic disc nucleus in its second configuration in the passageway of said disc nucleus implant instrument;

(e) introducing the dilator of said disc nucleus implant instrument into the hole in the disc annulus while said hole is not fully dilated;

(f) causing said dilator to dilate, and thus to more fully dilate the hole in the disc annulus;

(g) passing said prosthetic disc nucleus through said dilator and into said disc nucleus space while the disc annulus is more fully dilated and the prosthetic disc nucleus is in its second configuration;

(h) withdrawing said disc nucleus implant instrument and allowing said disc annulus to return to a size smaller than its dilated size;

(i) causing or allowing said prosthetic disc nucleus to assume its first configuration.

17. The method of claim 16 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate; and wherein the method further includes the step of activating the activator to dilate the dilator.

18. The method of claim 17 wherein said activator includes a lever for activating said dilator.

19. The method of claim 17 wherein said activator includes an inclined plane for activating said dilator.

20. The method of claim 17 wherein said activator includes a screw for activating said dilator.

21. The method of claim 16 wherein said dilator comprises at least two arms for dilating a hole in a disc annulus.

22. The method of claim 21 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate; and wherein the method further includes the step of activating the activator to move at least one of said at least two arms to dilate a hole in a disc annulus.

23. The method of claim 22 wherein said activator includes a lever for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

24. The method of claim 22 wherein said activator includes an inclined plane for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

25. The method of claim 22 wherein said activator includes a screw for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

26. The method of claim 22 wherein at least one of said at least two arms is fixed with respect to said passageway for passing a prosthetic disc nucleus.

27. The method of claim 22 wherein at least two of said at least two arms are movable with respect to said passageway for passing a prosthetic disc nucleus.

28. The method of claim 16 wherein said disc nucleus implant instrument further includes a locking mechanism for holding said dilator in a dilating position.

29. The method of claim 16 wherein said prosthetic disc nucleus comprises a load bearing elastic body having shape memory and sized for placement into an intervertebral disc space, said body having a first end, a second end, and a central portion; wherein said shape memory biases said body to a first configuration wherein said first end and said second end are positioned adjacent to said central portion to form at least one inner fold and to provide a substantially solid center core when the implant is in its first configuration; said elastic body configurable into a second, straightened configuration for insertion through an opening in an intervertebral disc annulus fibrosis; wherein said shape memory returns said body to said first configuration after said insertion.

30. The method of claim 16 wherein said prosthetic disc nucleus comprises a load bearing elastic body sized for placement into an intervertebral disc space, said body having a first end, a second end, a central portion, and a first configuration wherein said first end and said second end are positioned adjacent to said central portion to form at

least one inner fold, said elastic body configurable into a second, straightened configuration for insertion through an opening in an intervertebral disc annulus fibrosis, said body configurable back into said first configuration after said insertion; wherein said elastic body has a surface that includes wrinkles, indents or projections that relieve stress and prevent cracking or tearing of the implant when the implant is straightened for implantation.

31. A device for implanting a prosthetic spinal disc nucleus, comprising:
- (a) a first channel member having a first end and a second end, said first channel member defining a channel from said first end to said second end, said channel comprising at least one side wall;
  - (b) a post extending radially inward from said first channel member side wall, said post being located near the first end of said first channel member;
  - (c) a second channel member having a first end and a second end, said second channel member defining a channel from said first end to said second end, said channel comprising at least one side wall;
  - (d) a post extending radially inward from said second channel member side wall, said post being located near the first end of said second channel member;
- wherein said first channel member and said second channel member are pivotally connected at their respective first ends;
- wherein the device assumes a loading configuration when the first channel member and the second channel member are pivotally connected to define an angle of less than 180 degrees; and

wherein the device assumes an implanting configuration when the first channel member and the second channel member are pivotally connected to define an angle of approximately 180 degrees.

32. The device of claim 31 and further including a locking mechanism to lock the device into its implanting configuration.

33. The device of claim 31 wherein the second end of said first channel member terminates in a tip compressible to a cross section smaller than the cross section of the first end of said first channel member.

34. The device of claim 33 wherein said tip comprises at least two arms.

35. The device of claim 34 wherein at least one of said at least two arms includes teeth.

36. The device of claim 34 wherein at least one of said at least two arms is rigid, and at least one of said at least two arms is flexible.

37. The device of claim 33 wherein said tip comprises a pair of opposing arms.

38. The device of claim 37 wherein at least one of said pair of opposing arms is shorter than the other of said pair of opposing arms.

39. A disc nucleus implant instrument comprising:

(a) a passageway effective for passing a material for replacing or augmenting an intervertebral disc nucleus, said passageway having a proximal end and a distal end; and

(b) a dilator at the distal end of said passageway, said dilator being effective for dilating an opening in a disc annulus.



40. The disc nucleus implant instrument of claim 39 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate.

41. The disc nucleus implant instrument of claim 40 wherein said activator includes a lever for activating said dilator.

42. The disc nucleus implant instrument of claim 40 wherein said activator includes an inclined plane for activating said dilator.

43. The disc nucleus implant instrument of claim 40 wherein said activator includes a screw for activating said dilator.

44. The disc nucleus implant instrument of claim 39 wherein said dilator comprises at least two arms for dilating a hole in a disc annulus.

45. The disc nucleus implant instrument of claim 44 wherein at least one of said at least two arms is fixed with respect to said passageway for passing a prosthetic disc nucleus.

46. The disc nucleus implant instrument of claim 44 wherein at least two of said at least two arms are movable with respect to said passageway for passing a prosthetic disc nucleus.

47. The disc nucleus implant instrument of claim 44 wherein said disc nucleus implant instrument further includes an activator for causing the dilator to dilate.

48. The disc nucleus implant instrument of claim 47 wherein at least one of said at least two arms is fixed with respect to said passageway for passing a prosthetic disc nucleus.

49. The disc nucleus implant instrument of claim 47 wherein at least two of said at least two arms are movable with respect to said passageway for passing a prosthetic disc nucleus.

50. The disc nucleus implant instrument of claim 47 wherein said activator includes a lever for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

51. The disc nucleus implant instrument of claim 47 wherein said activator includes an inclined plane for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

52. The disc nucleus implant instrument of claim 47 wherein said activator includes a screw for activating said dilator and for causing at least one of said at least two arms to move and to dilate a hole in a disc annulus.

53. The disc nucleus implant instrument of claim 39 wherein said disc nucleus implant instrument further includes a locking mechanism for holding said dilator in a dilating position.

54. The device of claim 44 wherein at least one of said pair of opposing arms is shorter than the other of said pair of opposing arms.

55. A method of implanting a material into an intervertebral disc space defined by adjacent vertebrae; said method comprising:

(a) providing an implanting instrument having:

(i) a passageway effective for passing a material suitable for implantation into an intervertebral disc nucleus, said passageway having a proximal end and a distal end; and

(ii) an one arm at the distal end of said passageway; said arm having a width approximately equal to the desired height of the intervertebral disc space;

(b) providing a material suitable for implantation into an intervertebral disc space in the passageway of said implanting instrument;

(c) inserting said implanting instrument into the intervertebral disc space in an orientation in which said arm is generally parallel to the plane of the intervertebral disc space;

(d) turning said implanting instrument by about 90 degrees so that said arm is generally perpendicular to the plane of the intervertebral disc space, thus distracting the adjacent vertebrae;

(e) passing said material suitable for implantation into an intervertebral disc space through said implanting instrument and into said intervertebral disc space; and

(g) withdrawing said implanting instrument and allowing said material suitable for implantation into an intervertebral disc space to occupy said intervertebral disc space.

56. The method of claim 55 wherein said inserting step is accomplished without distracting the adjacent vertebrae.

57. The method of claim 55 wherein said method comprises the steps of:

(a) providing an implanting instrument having:

(i) a passageway effective for passing a material for replacing or augmenting an intervertebral disc nucleus, said passageway having a proximal end and a distal end; and

(ii) a dilator at the distal end of said passageway, said dilator being effective for dilating an opening in a disc annulus, and said dilator comprising at least one arm having a width approximately equal to the desired height of the intervertebral disc space;

(b) providing a material suitable for implantation into an intervertebral disc space in the passageway of said implanting instrument;

(c) providing a hole in the annulus of a disc receiving the material for replacing or augmenting an intervertebral disc nucleus, said hole having an undilated size that is smaller than the cross-sectional size of the material for replacing or augmenting an intervertebral disc nucleus, and said hole having a dilated size that is larger than the cross-sectional size of the material for replacing or augmenting an intervertebral disc nucleus;

(d) inserting said implanting instrument into the intervertebral disc space in an orientation in which said arm is generally parallel to the plane of the intervertebral disc space, wherein said inserting step further introduces the dilator of said disc nucleus implant instrument into the hole in the disc annulus while said hole is not fully dilated;

(e) turning said implanting instrument by about 90 degrees so that said arm is generally perpendicular to the plane of the intervertebral disc space, thus distracting the adjacent vertebrae;

(f) causing said dilator to dilate, and thus to dilate the hole in the disc annulus;

(g) passing said material suitable for implantation through said dilator and into said disc nucleus space while the hole in said disc annulus is dilated; and

(h) withdrawing said disc nucleus implant instrument and allowing said hole in said disc annulus to return to a size smaller than its dilated size.

58. The method of claim 55 wherein said method comprises the steps of:

(a) providing an implanting instrument having:

(i) passageway effective for passing a material for replacing or augmenting an intervertebral disc nucleus, said passageway having a proximal end and a distal end; and

(ii) a dilator at the distal end of said passageway, said dilator being effective for dilating an opening in a disc annulus, and said dilator comprising at least one arm having a width approximately equal to the desired height of the intervertebral disc space;

(b) providing a material suitable for implantation into an intervertebral disc space in the passageway of said implanting instrument, wherein said material comprises a prosthetic disc nucleus having a first configuration and a second configuration, wherein said first configuration presents a first cross-sectional size and said second configuration presents a second cross-sectional size, wherein said first cross-sectional size is larger than said second cross-sectional size;

(c) providing a hole in the annulus of a disc receiving the prosthetic disc nucleus, said hole having an undilated size that is smaller than the first cross-sectional size of said prosthetic disc nucleus, and said hole having a dilated size that is larger than the second cross-sectional size of said prosthetic disc nucleus;

(d) inserting said implanting instrument into the intervertebral disc space in an orientation in which said arm is generally parallel to the plane of the intervertebral disc space, wherein said inserting step further introduces the dilator of said disc nucleus implant instrument into the hole in the disc annulus while said hole is not fully dilated;

(e) turning said implanting instrument by about 90 degrees so that said arm is generally perpendicular to the plane of the intervertebral disc space, thus distracting the adjacent vertebrae;

(f) causing said dilator to dilate, and thus to dilate the hole in the disc annulus;

(g) passing said prosthetic disc nucleus through said dilator and into said disc nucleus space while the disc annulus is dilated and the prosthetic disc nucleus is in its second configuration;

(h) withdrawing said disc nucleus implant instrument and allowing said hole in said disc annulus to return to a size smaller than its dilated size; and

(i) causing or allowing said prosthetic disc nucleus to assume its first configuration.